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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/076,306	02/12/2002	Jan Urban Kristoffer Hellstrand	MAXIM.026C3	1217

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EXAMINER

CANELLA, KAREN A

ART UNIT PAPER NUMBER

1643

DATE MAILED: 06/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/076,306

Applicant(s)

HELLSTRAND ET AL.

Examiner

Karen A. Canella

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-8 and 11-16 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 1-8, 11-16 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. Claims 1 and 8 have been amended. Claim 9 has been canceled. Claims 1-8 and 11-16 are pending and under consideration.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1-8 and 11-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-8 and 11-16 are methods dependent upon the identity of an analog of flavone acetic acid (FAA). The art recognizes the term "analog" to indicate that the substance has a functional similarity, but is not held to be similar in structure. thus the claims are thus dependent upon a genus of FAA analog molecules which is not limited by a structural similarity to flavone acetic acid. Thus, the disclosure of Flavone Acetic Acid cannot adequately describe the genus of FAA analogs because there is no nexus between the structure of FAA and a FAA analog which can be any molecule which functions as FAA in the activation of NK cells. One of skill in the art would reasonably conclude that applicant was not in possession of the genus of FAA analogs on which the instant method claims depend.

4. The rejection of claims 1-3, 6 and 7 under 35 U.S.C. 103(a) as being unpatentable over Hellstrand et al (WO 91/04037) in view of the abstract of Oleksowicz et al (Am J Ther. 1994 Aug;1(2):107-115) is maintained for reasons of record

Claim 1 is drawn in part to a method of inhibiting tumor growth in a subject comprising administering to a subject with a neoplastic disease in need thereof an effective amount of a NK-cell activating cytokine, wherein said cytokine is selected from Il-1, Il-12, IFN-beta, IFN-gamma and an effective amount of a compound which inhibits the production or release of hydrogen peroxide selected from the group consisting of histamine, other H2 receptor agonists and

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serotonin, and wherein the NK activating cytokine is not IL-2 or IFN alpha. Claim 2 embodies the method of claim 1 wherein the administration of said NK activating cytokine and said compounds is performed simultaneously. Claim 3 embodies the method of claim 1 wherein the administration of said compound is performed within 24 hours of the administration of said NK cell activating cytokine. Claim 6 embodies the method of claim 1 wherein said histamine, other H2 receptor agonist or serotonin is administered parentally to said subject.

Hellstrand et al teach a method of treating a neoplastic disease in a subject comprising the administration of histamine or other H2 receptor agonist in combination with the administration of the cytokine Il-2 (page 7, lines 9-18). Hellstrand et al teach that the compounds can be administered in the same composition (page 6, lines 31-33) or in separate compositions within the same day (page 11, lines 19-21), thus fulfilling the specific embodiments of claims 2 and 3. Hellstrand et al teach that the amount of histamine is 0.1 to 10 mg/day (page 9, lines 9-13), thus fulfilling the specific embodiment of claim 6. Hellstrand et al teach the parenteral administration of the histamine and Il-2 (page 8, lines 7-8), which fulfills the specific embodiment of claim 7. Hellstrand et al do not teach a NK activating cytokine other than Il-2.

Oleksowicz et al teach that IL-12 has been shown to enhance the lytic activity of nonspecific NK/LAK cells and appears to be more efficient than IL-2 or IFNs in enhancing NK cytotoxicity.

It would have been prima facie obvious at the time the claimed invention was made, to substitute Il-2 for Il-2 in the method of treating tumor growth taught by Hellstrand et al. One of skill in the art would have been motivated to do so by the teachings of the abstract of Oleksowicz et al on the enhanced ability of Il-12 to stimulate NK cell cytotoxicity relative to Il-2.

5. Applicant argues that there is no motivation to combine the references. this has been considered but not found persuasive. Oleksowicz et al teach Il-12 is superior in the enhancement of NK cytotoxicity. It is concluded that this is ample motivation and that it is only required that the combination have a reasonable expectation of success, therefore applicants argument regarding the probability of success are not persuasive. Applicant further argues that the combination provides unexpectedly superior results. This has been considered but not found persuasive. It is noted that the instant claims do not incorporate a specific limitation with

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regarding to the unexpected results. further, applicants arguments that the enhances NK cytotoxicity against tumor cell is not persuasive, because Oleksowicz et al teach that IL-12 has been shown to enhance the lytic activity of nonspecific NK/LAK cells and appears to be more efficient than IL-2 or IFNs in enhancing NK cytotoxicity.

6. All other rejections an objections as set forth or maintained in the prior office action are withdrawn in light of applicants amendments.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Karen A. Canella, Ph.D.

6/11/2006


KAREN A. CANELLA PH.D.
PRIMARY EXAMINER